Alabama Medicaid DUR Board Meeting
Minutes
January 25, 2006

Attendees: Rob Colburn, Christina Daniels, Darin Elliott, Kevin Green, Clemice Hurst, Jimmy Jackson, Kelli Littlejohn, Tiffany Minnifield, Bernie Olin, Steven Rostand, Kevin Royal, John Searcy, Paula Thompson

Members Absent: Rhonda Harden

Rob Colburn, Chairman, called the meeting to order at 1:00pm.

Review and Adoption of Minutes of October 26, 2005 meeting: Rob Colburn asked if there were any additions, deletions or changes to the minutes of the October 26, 2005 meeting. No changes or additions were brought to the attention of the Board. Rob asked for a motion to approve the minutes as presented. Paula Thompson so moved and Steven Rostand seconded. The motion passed by a voice vote with no audible dissenters. The minutes were adopted as written.

DUR Update: Christina Daniels began the DUR update by reviewing the following reports: Monthly PAs and Overrides, PAs and Overrides by Source, Monthly Help Desk Reports and PA Response Time Ratio Reports for September, October and November 2005. Christina noted an increase in the number of emergency brand early refill approvals in September likely due to hurricane Katrina. A question was raised regarding the declining approval rate for PAs. Christina explained that the percentage is going down due to classes added to electronic PA, but that the overall number of approvals has remained consistent. Responding to an inquiry regarding the 460 Synagis approvals in September, Christina noted that some children have more than one PA on file, due to changes in dose related to weight changes, thus the 460 approvals do not represent the number of unique recipients. Christina noted one MAC override for the reporting period. She also noted one acne approval for the same reporting period. The patient did not have an acne diagnosis. The appeal was filed and supported by peer review literature.

Christina then presented the following reports: Top 25 Drugs by Claim, Top 25 Drugs by Cost and Top 15 Therapeutic Classes. These reports were included in the DUR packet as an addendum in response to a request made at the last DUR meeting. These reports will be included in future DUR packets.

Quarterly Reports: Christina Daniels briefly reviewed the Alabama Medicaid Program Summary reports for the quarters April 1, 2005 through June 30, 2005 and July 1, 2005 through September 30, 2005. Christina then presented the Cost Management Analysis reports. According to November 2005 Drug Benefit Trends, an increase of 9.9% is anticipated in the private sector for 2006. Medicaid cost increases remain steady at approximately 2%.

Intervention Activity Report: Christina Daniels reported that the RDUR Intervention for third quarter 2005 was dose optimization and tablet splitting. She noted that the date of intervention was October 3, 2005. She reported 420 profiles reviewed, 387 cases identified, 471 letters generated, one letter deleted in QA, and 470 letters sent. Of those 470 letters sent, 25 were attributed to drug/disease interaction, 147 to drug/drug conflicts, 12 to clinical appropriateness, 138 to over-utilization and four to possible non-compliance. There were 320 unique recipients identified. A discussion followed regarding provider response to the October intervention. Approximately 120 letters were returned, with 26 prescribers agreeing to modify therapy.

Proposed Criteria: Christina Daniels requested that the Board continue with dose optimization criteria and add tablet splitting criteria for the next intervention cycle. For the April cycle, she proposed that the Board consider utilization of carisoprodol. The P & T Committee referred this matter to the DUR Board as carisoprodol is only indicated for short term use and use beyond that has been shown to increase risk of addiction. Christina then reviewed 46 sets of criteria to be added to the base set.

Medicaid Update: Kelli Littlejohn presented a brief Medicaid update. Kelli reported that the minutes from the last P & T meeting are available on the web. The next P & T meeting is scheduled for February 22 and is tentatively planned for the 8th floor conference room in the Medicaid Building. The P & T meeting will include re-reviews of cardiac agents, platelet aggregation inhibitors and antihyperlipidemics.

Kelli reported that on January 1, 2006 Medicaid stopped coverage of any drug for sexual or erectile dysfunction. She noted exceptions for medical necessity. She also reported that on January 1, full duals were transferred to Medicare Part D. Kelli reported that on January 20 Medicaid provided a monetary advance for pharmacies. Those amounts were based on December 2005 dual eligible disbursements and will be recouped from March, April and May check writes. Due to the large monetary amounts and the time required to recoup those amounts, long term care facilities were required to sign promissory notes for the advance. On January 20, an Alert was issued notifying the provider community that the PA requirement has temporarily been lifted for Relenza and Tamiflu. The PA requirement will be reinstated on April 1. The Quarterly PDL update, formerly scheduled for January 1, will take effect February 1. The updates include implementation of the EENT vasoconstrictor, EENT antiallergy, and macrolide classes. As of February 1, generic omeprazole will require a PA; however, Prilosec OTC and current preferred brands will remain preferred agents.

Tiffany Minnifield continued with the Medicaid update. She stated that on February 1 the MPSs will begin distributing the Medicaid Pharmacy Summary to physicians. She also informed the Board that future DUR meeting agendas will be posted on-line prior to meeting dates. Tiffany updated the Board regarding the on-line electronic PA request. She reminded members that three seats remain vacant on the DUR Board. She also noted that the position of Vice Chair remains open and, per DUR bylaws, must be filled by a physician, as the Chair is a pharmacist. Two physicians are eligible; Dr. Green and Dr.

Rostand. Dr. Rostand asked to be removed from consideration as he will not renew his membership on the Board at the end of his term. Tiffany asked Dr. Green to accept the Vice Chair position. Dr. Green accepted. There being no other eligible members to be considered for the position, no vote was taken and Dr. Green was welcomed as the new Vice Chair. Tiffany reminded members to complete travel vouchers and update e-mail addresses before leaving the meeting.

Rob Colburn asked for suggestions for the next meeting date. The next meeting was tentatively scheduled for April 26, at 1:00pm. There being no further business brought to the attention of the Board, the meeting was adjourned at approximately 2:30pm.

Immediately following the meeting, ballots were tabulated. All criteria were approved unanimously by all eight voting members. Results will be announced at the next DUR meeting.

Respectfully submitted,

Christina Daniels, Pharm.D.

BALLOT
CRITERIA RECOMMENDATIONS (October)
January 25, 2006

Criteria Recommendations	Approved	Approve as Amended	Rejected
1. Promethazine / Patients less than 2 years of age **Alert Message:** Promethazine is contraindicated for use in pediatric patients less than two years of age because of the potential for fatal respiratory depression. Respiratory depression and apnea, sometimes associated with death, are strongly associated with promethazine products and are not directly related to individualized weight-based dosing, which might otherwise permit safe administration. **Conflict Code:** TA – Therapeutic Appropriateness (Boxed Warning) **Drug/ Disease:** Util A Util B Util C Promethazine **Age Range**: <2 years of age **References:** Phenergan Prescribing Information, Dec. 2004, Wyeth Pharmaceuticals Inc. MedWatch: FDA Safety Information and Adverse Event Reporting Program, 2005.	√√√√ √√√√	_____	_____
2. Promethazine / Pediatric Patients 2 years and older **Alert message:** Caution should be exercised when administering promethazine to pediatric patients 2 years of age and older. It is recommended that the lowest effective dose of promethazine be used in pediatric patients 2 years of age and older and concomitant administration of other drugs with respiratory depressant effects be avoided. **Conflict Code:** TA – Therapeutic Appropriateness (Boxed Warning) **Drug/ Disease:** Util A Util B Util C Promethazine **Age Range:** 2 – 18 years **References**: Phenergan Prescribing Information, Dec. 2004, Wyeth Pharmaceuticals Inc.	√√√√ √√√√	_____	_____
3. Tizanidine / Fluvoxamine **Alert Message:** Concurrent use of tizanidine with fluvoxamine, a potent CYP1A2 inhibitor, is contraindicated. Significant alterations of pharmacokinetic parameters of tizanidine including AUC, t1/2, Cmax, increased oral bioavailability and decreased plasma clearance have been observed with concomitant fluvoxamine administration. Coadministration of these agents has resulted in profound hypotension, bradycardia and excessive drowsiness. **Conflict Code:** DD – Drug/Drug Interaction **Drug/Disease:** Util A Util B Util C Tizanidine Fluvoxamine **References:** Zanaflex Prescribing Information, April 2005, Athena Neurosciences. Micromedex Healthcare Series, Drugdex Drug Evaluations, 2005	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approved as Amended	Rejected
4. Tizanidine / CYP1A2 Inhibitors **Alert Message:** Caution is recommended when considering concomitant use of tizanidine with other inhibitors of CYP1A2, such as antiarrhythmics (amiodarone, mexiletine, propafenone), cimetidine, fluoroquinolones (ciprofloxacin, norfloxacin) and ticlopidine. The concurrent use of these agents may increase the risk of profound hypotension, somnolence and dizziness. **Conflict Code:** DD - Drug/Drug Interaction **Drug/Disease:** Util A: Tizanidine Util B: Amiodarone, Mexiletine, Propafenone, Cimetidine Util C: Ciprofloxacin, Norfloxacin, Ticlopidine **References:** Granfors MT, Backman JT, Neuvonen M, et. al. Ciprofloxacin greatly increases concentrations and hypotensive effect of tizanidine by inhibiting its cytochrome P450 1A2-mediated presystemic metabolism. Clin Pharmacol Ther. 2004 Dec;76(6):598-606. Zanaflex Prescribing Information, April 2005, Athena Neurosciences.	√√√√ √√√√	_____	_____
5. Darifenacin / Hepatic Impairment **Alert Message:** The daily dose of Enablex (darifenacin) should not exceed 7.5 mg once daily for patients with moderate hepatic mpairment. Darifenacin is not recommended for use in patients with severe hepatic impairment. Conflict Code: ER - Overutilization **Drug/Disease:** Util A: Darifenacin Util C: Hepatic Impairment **Max Dose:** 7.5 mg/day **References:** Micromedex Healthcare Series, Drugdex Drug Evaluations, 2005. Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
6. Darifenacin / CYP2D6 Substrates **Alert Message:** Caution should be exercised when Enablex (darifenacin), a moderate 2D6 inhibitor, is used concomitantly with medications that are predominantly metabolized by CYP2D6 and which have a narrow therapeutic window (e.g. flecainide and thioridazine). Concurrent use with darifenacin may result in elevated plasma concentrations of the substrates and increase risk of adverse effects. **Conflict Code:** DD – Drug/Drug Interaction **Drug/Disease:** Util A: Darifenacin Util B: Flecainide, Thioridazine **References:** Facts & Comparisons, 2005 Updates. Enablex Prescribing Information, Dec. 2004, Novartis Pharmaceuticals, Inc.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approved as Amended	Rejected
7. Darifenacin / Digoxin **Alert Message:** Caution should be exercised when Enablex (darifenacin) is used concomitantly with digoxin. Concurrent use of darifenacin (30mg daily) with digoxin (0.25mg) at steady state resulted in a 16% increase in digoxin exposure. Routine monitoring of digoxin should continue. **Conflict Code:** DD – Drug/Drug Interaction **Drug/Disease:** Util A: Darifenacin Util B: Digoxin Util C: **References:** Facts & Comparisons, 2005 Updates. Enablex Prescribing Information, Dec. 2004, Novartis Pharmaceuticals, Inc.	√√√√ √√√√	_____	_____
8. Darifenacin / Narrow Angle Glaucoma **Alert Message:** Enablex (darifenacin), an anticholinergic agent, should be used with caution in patients being treated for narrow-angle glaucoma and only when the potential benefits outweigh the risks. Darifenacin is contraindicated in patients with uncontrolled narrow-angle glaucoma. Conflict Code: MC – Drug Actual Disease Precaution **Drug/Disease:** Util A: Darifenacin Util B: Narrow-angle Glaucoma Util C: **References:** Facts & Comparisons, 2005 Updates. Enablex Prescribing Information, Dec. 2004, Novartis Pharmaceuticals, Inc.	√√√√ √√√√	_____	_____
9. Darifenacin / Urinary Retention **Alert Message:** Enablex (darifenacin), an anticholinergic agent, is contraindicated in patients with urinary retention or gastric retention and in patients who are at risk for these conditions. **Conflict Code:** MC – Drug Actual Disease Precaution **Drug/Disease:** Util A: Darifenacin Util B: Urinary Retention Gastric Retention Util C: **References:** Facts & Comparisons, 2005 Updates. Enablex Prescribing Information, Dec. 2004, Novartis Pharmaceuticals, Inc.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approved as Amended	Rejected
10. Darifenacin / GI Obstruction-Decreased GI Motility **Alert Message:** Enablex (darifenacin), an anticholinergic agent, should be administered with caution to patients with GI obstructive disorders because of the risk of gastric retention. Darifenacin, like other anticholinergic drugs, may decrease GI motility and should be used with caution in patients with severe constipation, ulcerative colitis, and myasthenia gravis. Conflict Code: DB – Drug/Drug marker and/or Diagnosis **Drug/Disease:** Util A: Darifenacin Util B: Ulcerative Colitis; Myasthenia Gravis; Intestinal Obstruction; Slow Transit Constipation Util C: **References:** Facts & Comparisons, 2005 Updates. Enablex Prescribing Information, Dec. 2004, Novartis Pharmaceuticals, Inc.	√√√√ √√√√	_____	_____
11. Anticholinergic Agents / Therapeutic Duplication **Alert Message:** The concomitant use of anticholinergic agents may increase the frequency and/or severity of dry mouth, constipation, blurred vision and other anticholinergic adverse effects. **Conflict Code:** TD – Therapeutic Duplication **Drug/Disease:** Util A: Belladonna; Atropine; Scopolamine; Homatropine; Flavoxate; Hyoscyamine; Glycopyrrolate; Mepenzolate; Propantheline; Dicyclomine; Clidinium Util B: Benztropine; Biperiden; Procyclidine; Trihexyphenidyl; Darifenacin; Oxybutynin; Tolterodine; Trospium; Solifenacin; Orphenadrine Util C: **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approved as Amended	Rejected
12. Solifenacin / High Dose **Alert Message:** Vesicare (solifenacin) may be over-utilized. The recommended maximum dose is 10 mg per day. Higher doses have resulted in a higher incidence of adverse reactions. **Conflict Code:** HD – High Dose **Drug/Disease:** Util A Util B Util C Solifenacin **Maximum Dose:** 10 mg/day **References:** Facts & Comparisons, 2005 Updates. Micromedex Healthcare Series, Drugdex Drug Evaluations, 2005.	√√√√ √√√√	_____	_____
13. Solifenacin / Hepatic Impairment **Alert Message:** The daily dose of Vesicare (solifenacin) should not exceed 5 mg for patients with moderate hepatic impairment. Solifenacin is not recommended for use in patients with severe hepatic impairment. Conflict Code: ER - Overutilization **Drug/Disease:** Util A Util B Util C Solifenacin Hepatic Impairment **Max Dose:** 5 mg/day **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
14. Solifenacin / Renal Impairment **Alert Message:** The daily dose of Vesicare (solifenacin) should not exceed 5 mg for patients with severe renal impairment (Ccr less than 30 mL/min). Significant increases in the AUC and elimination half-life have been noted with single oral doses of solifenacin 10 mg and have been correlated to the degree of renal impairment. **Conflict Code:** ER - Overutilization **Drug/Disease:** Util A Util B Util C Solifenacin Chronic Renal Failure **Max Dose:** 5 mg/day **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approve as Amended	Rejected
15. Solifenacin / Potent 3A4 Inhibitors **Alert Message:** The daily dose of Vesicare (solifenacin), a CYP 3A4 substrate, should not exceed 5 mg when coadministered with a potent CYP3A4 inhibitor (e.g. ketoconazole, itraconazole, ritonavir, nelfinavir, clarithromycin, and nefazodone). Exceeding the recommended dose during concurrent therapy may increase the risk of adverse effects. **Conflict Code:** DD – Drug/Drug Interaction **Drug/Disease:** Util A: Darifenacin Util B: Util C: Ketoconazole, Itraconazole, Ritonavir, Nelfinavir, Clarithromycin, Nefazodone, Erythromycin, Troleandomycin, Indinavir **Max Dose:** 5 mg/day **References:** Facts & Comparisons, 2005 Updates. Vesicare Prescribing Information, Nov. 2004 GlaxoSmithKline.	√√√√ √√√√	_____	_____
16. Solifenacin / Narrow Angle Glaucoma **Alert Message:** Vesicare (solifenacin), an anticholinergic agent, should be used with caution in patients being treated for narrow-angle glaucoma and only when the potential benefits outweigh the risks. Solifenacin is contraindicated in patients with uncontrolled narrow-angle glaucoma. **Conflict Code:** MC – Drug Actual Disease Precaution **Drug/Disease:** Util A: Solifenacin Util B: Narrow-angle Glaucoma Util C: **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
17. Solifenacin / Urinary Retention & Gastric Retention **Alert Message:** Vesicare (solifenacin), an anticholinergic agent, is contraindicated in patients with urinary retention or gastric retention and in patients who are at risk for these conditions. **Conflict Code:** MC – Drug Actual Disease Precaution **Drug/Disease:** Util A: Solifenacin Util B: Urinary Retention, Gastric Retention Util C: **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approve as Amended	Rejected
18. Solifenacin / GI Obstruction-Decreased GI Motility **Alert Message:** Vesicare (solifenacin), an anticholinergic agent, should be administered with caution to patients with GI obstructive disorders because of the risk of gastric retention. Solifenacin, like other anticholinergic drugs, may decrease GI motility and should be used with caution in patients with constipation, ulcerative colitis, and myasthenia gravis. **Conflict Code:** DB – Drug/Drug marker and/or Diagnosis **Drug/Disease:** Util A: Solifenacin Util B: Ulcerative Colitis; Myasthenia Gravis; Intestinal Obstruction; Slow Transit Constipation Util C: **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
19. Solifenacin / QT Prolongation & QT Prolongation Drugs **Alert Message:** Vesicare (solifenacin) should be administered with caution to patients with a history of QT prolongation or who are on medications known to prolong the QT interval. A significant period effect on QTc has been observed following the administration of solifenacin (10 or 30 mg) in healthy female volunteers. The QT prolonging effect was greater with the 30 mg dose as compared with the 10 mg dose and did not appear to be as great as that of the positive control moxifloxacin at its therapeutic dose. **Conflict Code:** DB – Drug/Drug marker and/or Diagnosis **Drug/Disease:** Util A: Solifenacin Util B: QT Prolongation ICD-9s; Quinidine; Thioridazine; Mefloquine; Chlorpromazine; Moxifloxacin; Gatifloxacin; Procainamide; Mesoridazine; Pentamidine; Levofloxacin; Tacrolimus; Ziprasidone; Disopyramide; Droperidol; Amiodarone; Pimozide; Bretylium; Sotalol; Dofetilide; Sparfloxacin Util C: **References:** Facts & Comparisons, 2005 Updates. Vesicare Prescribing Information, Nov. 2004, GlaxoSmithKline.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approve as Amended	Rejected
20. Tolterodine IR & XL / High Dose **Alert Message:** Detrol/Detrol LA (tolterodine) may be over-utilized. The manufacturer's recommended dose is 4 mg daily. Conflict Code: HD – High Dose **Drug/Disease:** Util A: Tolterodine Util B: Util C: **Max Dose:** 4 mg/day **References:** Facts & Comparisons, 2005 Updates. Detrol LA Prescribing Information, April 2004, Pfizer, Inc.	√√√√ √√√√	_____	_____
21. Tolterodine IR / Hepatic Impairment **Alert Message:** The daily dose of Detrol or Detrol LA (tolterodine) should not exceed 2 mg for patients with significantly reduced hepatic or renal function. **Conflict Code:** HD – High Dose **Drug/Disease:** Util A: Tolterodine Util B: Util C (Inclusive): Hepatic Impairment, Renal Impairment, Lanthanum, Sevelamer, Doxercalciferol, Paricalcitol, Calcitriol **Max Dose:** 2 mg/day **References:** Facts & Comparisons, 2005 Updates. Detrol LA Prescribing Information, April 2004, Pfizer, Inc.	√√√√ √√√√	_____	_____
22. Tolterodine / Potent 3A4 Inhibitors **Alert Message:** The daily dose of Detrol/ Detrol LA (tolterodine), a CYP 3A4 substrate, should not exceed 2 mg when coadministered with a potent CYP3A4 inhibitor (e.g. ketoconazole, itraconazole, erythromycin, clarithromycin, cyclosporine and vinblastine). Exceeding the recommended dose during concurrent therapy may increase the risk of adverse effects of tolterodine. **Conflict Code:** HD - High Dose (drug/drug Interaction) **Drug/Disease:** Util A: Tolterodine Util B: Util C (Inclusive): Ketoconazole, Erythromycin, Itraconazole, Cyclosporine, Ritonavir, Troleandomycin, Nelfinavir, Indinavir, Clarithromycin, Vinblastine, Nefazodone, Cyclosporine **Max Dose:** 2 mg/day **References:** Facts & Comparisons, 2005 Updates. Detrol LA Prescribing Information, April 2004, Pfizer, Inc. Detrol Prescribing Information, July 2003, Pfizer, Inc.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approve as Amended	Rejected
23. Oxybutynin / High Dose (Adults) **Alert Message:** Ditropan (oxybutynin immediate-release) may be over-utilized. The manufacturer's recommended maximum dose is 5 mg 4 times per day. **Conflict Code:** HD – High Dose **Drug/Disease:** Util A Util B Util C Oxybutynin IR **Age Range:** 18 years and older **Max Dose:** 20 mg/day **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
24. Oxybutynin / High Dose (Pediatric) **Alert Message:** Ditropan (oxybutynin immediate-release) may be over-utilized. The manufacturer's recommended maximum dose is 5 mg 3 times per day. **Conflict Code:** HD – High Dose **Drug/Disease:** Util A Util B Util C Oxybutynin IR **Age Range:** 5 – 18 years **Max Dose:** 15 mg/day **References:** Facts & Comparisons, 2005 Updates. Ditropan Prescribing Information, Sept. 2003, Ortho-McNeil Pharmaceuticals, Inc.	√√√√ √√√√	_____	_____
25. Oxybutynin Extended Release / High Dose **Alert Message:** Ditropan XL (oxybutynin extended-release) may be over-utilized. The manufacturer's recommended maximum dose is 30 mg per day. **Conflict Code:** HD – High Dose **Drug/Disease:** Util A Util B Util C Oxybutynin XL **Max Dose:** 30 mg/day **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
26. Oxybutynin / Hepatic & Renal Impairment **Alert Message:** Ditropan/Ditropan XL/ (oxybutynin) should be used with caution in patients with renal or hepatic impairment. **Conflict Code:** DB – Drug-Drug Marker and/or Diagnosis **Drug/Disease:** Util A Util B Util C Oxybutynin Renal Impairment Hepatic Impairment **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approve as Amended	Rejected
27. Oxybutynin Transdermal / High Dose **Alert Message:** Oxytrol (oxybutynin transdermal) may be over-utilized. The manufacturer's recommended dose is one 3.9 mg/day system applied twice weekly (every 3 to 4 days). Conflict Code: HD – High Dose **Drug/Disease**: Util A / Util B / Util C Oxybutynin Transdermal **Max Dose:** 3.9 mg/day **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
28. Oxybutynin / Contraindications **Alert Message:** Ditropan/Ditropan XL/Oxytrol (oxybutynin), an anticholinergic agent, is contraindicated in patients with urinary retention, gastric retention and other severe conditions of decreased gastrointestinal motility, uncontrolled narrow-angle glaucoma and in patients who are at risk for these conditions. **Conflict Code:** MC - Drug (Actual) Disease Contraindication/Precaution **Drug/Disease:** Util A: Oxybutynin Util B: Urinary Retention; Gastric Retention; Paralytic Ileus Util C: **References**: Ditropan Prescribing Information, March 2003, Ortho-McNeil Pharmaceuticals Inc. Micromedex Healthcare Series, Drugdex Drug Evaluations, 2005.	√√√√ √√√√	_____	_____
29. Oxybutynin / Disease State Precautions **Alert Message:** Ditropan/Ditropan XL (oxybutynin), an anticholinergic agent, should be used with caution in patients with hyperthyroidism, cardiac arrhythmia, congestive heart failure, coronary heart disease, hiatal hernia, hypertension, autonomic neuropathy, ulcerative colitis and prostatic hypertrophy. Oxybutynin may aggravate the symptoms of these conditions. **Conflict Code:** MC - Drug (Actual) Disease Precaution **Drug/Disease:** Util A: Oxybutynin Util B: Hyperthyroidism; Cardiac Arrhythmia; Congestive Heart Failure; Coronary Heart Disease; Hiatal Hernia; Hypertension; Ulcerative Colitis; Prostatic Hypertrophy Util C: **References:** Ditropan Prescribing Information, Mar. 2003, Ortho-McNeil Pharmaceuticals Inc. Micromedex Healthcare Series, Drugdex Drug Evaluations, 2005.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approve as Amended	Rejected
30. Oxybutynin / GI Obstruction-Decreased GI Motility **Alert Message:** Ditropan/Ditropan XL/Oxytrol (oxybutynin), an anticholinergic agent, should be administered with caution to patients with GI obstructive disorders because of the risk of gastric retention. Oxybutynin, like other anticholinergic drugs, may decrease GI motility and should be used with caution in patients with severe constipation, ulcerative colitis, and myasthenia gravis. **Conflict Code:** MC - Drug (Actual) Disease Precaution **Drug/Disease:** Util A: Oxybutynin Util B: Ulcerative Colitis; Myasthenia Gravis; Intestinal Obstruction; Slow Transit Constipation Util C: **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
31. Oxybutynin / GERD **Alert Message:** Ditropan/Ditropan XL/Oxytrol (oxybutynin) should be used with caution in patients who have gastrointestinal reflux or who are concurrently taking drugs (such as bisphosphonates) that can cause or exacerbate esophagitis. **Conflict Code:** DB – Drug/Drug marker and/or Diagnosis **Drug/Disease:** Util A: Oxybutynin Util B: GERD; Bisphosphonates; Potassium; NSAIDS; Iron; Quinidine; Doxycycline; Clindamycin; Tetracycline; Trimethoprim Util C: **References:** Facts & Comparisons, 2005 Updates. Ditropan Prescribing Information, March 2004, Ortho-McNeil Pharmaceuticals, Inc. Oxytrol Prescribing Information, Feb. 2003, Watson Pharma, Inc.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approve as Amended	Rejected
32. Flavoxate / High Dose **Alert Message:** Urispas (flavoxate) may be overutilized. The manufacturer's recommended maximum dose is 800 mg (200 mg 4 times a day). Conflict Code: HD – High Dose **Drug/Disease:** Util A: Flavoxate Util B: Util C: **Max Dose:** 800 mg/day **References:** Facts & Comparisons, 2005 Updates. Micromedex Healthcare Series, Drugdex Drug Evaluations, 2005.	√√√√ √√√√	_____	_____
33. Flavoxate / Contraindications **Alert Message:** Urispas (flavoxate), an anticholinergic agent, is contraindicated in patients who have pyloric or duodenal obstruction, obstructive intestinal lesions or ileus, achalasia, GI hemorrhage, or obstructive uropathies of the lower urinary tract. **Conflict Code:** MC – Drug (Actual Disease) Contraindication/Precaution **Drug/Disease:** Util A: Flavoxate Util B: Pyloric Obstruction; Duodenal Obstruction; Obstructive Intestinal Lesions or Ileus; Achalasia; GI Hemorrhage; Urinary obstruction Util C: **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approve as Amended	Rejected
34. Flavoxate / Glaucoma **Alert Message:** Urispas (flavoxate) should be used with caution in patients who have glaucoma. Flavoxate is an anticholinergic agent and use in these patients may aggravate the condition. **Conflict Code:** DB – Drug/Drug Marker and/or Diagnosis **Drug/Disease:** Util A: Flavoxate Util B: Glaucoma Util C: Latanoprost, Brimonidine, Travoprost, Apraclonidine, Bimatoprost, Dipivefrin, Carbachol, Levobunolol, Dorzolamide, Betaxolol, Brinzolamide, Metipranolol, Carteolol, Timolol, Levobetaxolol, Pilocarpine **References:** Micromedex Healthcare Series, Drugdex Drug Evaluations, 2005. Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
35. Trospium / High Dose **Alert Message:** Sanctura (trospium) may be over-utilized. The manufacturer's recommended daily dose is 20 mg twice daily. **Conflict Code:** HD – High Dose **Drug/Disease:** Util A: Trospium Util B: Util C: **Max Dose:** 40 mg/day **References:** Sanctura Prescribing Information, July 2004, Odyssey Pharmaceuticals, Inc. Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
36. Trospium / Renal Impairment **Alert Message:** The daily dose of Sanctura (trospium) should not exceed 20 mg once daily at bedtime for patients with severe renal impairment (CrCl less than 30 mL/min). A 4.5-fold and 2-fold increase in mean AUC and Cmax, respectively, and the appearance of an additional elimination phase with a long half-life (33hr) was detected in patients with severe renal sufficiency. **Conflict Code:** ER - Overutilization **Drug/Disease:** Util A: Trospium Util B: Util C: Chronic Renal Failure **Max Dose:** 20 mg/day **References:** Facts & Comparisons, 2005 Updates. Sanctura Prescribing Information, July 2004, Odyssey Pharmaceuticals, Inc.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approve as Amended	Rejected
37. Trospium / Urinary & Gastric Retention **Alert Message:** Sanctura (trospium), an anticholinergic agent, is contraindicated in patients with urinary retention or gastric retention and patients at risk for these conditions. **Conflict Code:** MC – Drug Actual Disease Precaution **Drug/Disease:** Util A: Trospium Util B: Urinary Retention; Gastric Retention Util C: **References:** Facts & Comparisons, 2005 Updates. Sanctura Prescribing Information, July 2004, Odyssey Pharmaceuticals, Inc.	√√√√ √√√√	_____	_____
38. Trospium / Narrow Angle Glaucoma **Alert Message:** Sanctura (trospium), an anticholinergic agent, should be used with caution in patients being treated for narrow-angle glaucoma and only when the potential benefits outweigh the risks. Trospium is contraindicated in patients with uncontrolled narrow-angle glaucoma. **Conflict Code:** MC – Drug Actual Disease Precaution **Drug/Disease:** Util A: Trospium Util B: Narrow-angle Glaucoma Util C: **References:** Facts & Comparisons, 2005 Updates. Sanctura Prescribing Information, July 2004, Odyssey Pharmaceuticals, Inc.	√√√√ √√√√	_____	_____
39. Trospium / GI Obstruction-Decreased GI Motility **Alert Message:** Sanctura (trospium) should be administered with caution to patients with GI obstructive disorders because of the risk of gastric retention. Trospium, like other anticholinergic drugs, may decrease GI motility and should be used with caution in patients with ulcerative colitis, intestinal atony and myasthenia gravis. **Conflict Code:** MC – Drug Actual Disease Precaution **Drug/Disease**: Util A: Trospium Util B: Ulcerative Colitis; Myasthenia Gravis; Intestinal Atony Util C: **References:** Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____

Criteria Recommendations	Approved	Approve as Amended	Rejected
40. Trospium / Drugs Eliminated by ATS **Alert Message:** Sanctura (trospium) is eliminated via active tubular secretion and has the potential for pharmacokinetic interactions with other drugs that are eliminated by the same route (e.g. digoxin, procainamide, morphine, vancomycin, metformin, and tenofovir). Coadministration of trospium with drugs that are eliminated by active tubular secretion may increase the serum concentration of trospium and/or the coadministered drug because of competition for this elimination pathway. Careful patient monitoring is recommended. **Conflict Code:** DD – Drug/Drug Interaction **Drug/Disease:** Util A: Trospium Util B: Digoxin, Procainamide, Morphine Util C: Vancomycin, Metformin, Tenofovir **References:** Facts & Comparisons, 2005 Updates. Sanctura Prescribing Information, July 2004, Odyssey Pharmaceuticals, Inc.	√√√√ √√√√	_____	_____
41. Telithromycin / Pimozide **Alert Message:** The concurrent use of Ketek (telithromycin) and pimozide is contraindicated due to increased risk of cardiotoxicity (e.g. QT prolongation, torsades de pointes, cardiac arrest). Although no formal drug interaction studies have been conducted, telithromycin may inhibit pimozide CYP 3A4-mediated metabolism causing elevated plasma levels. Both agents are known to cause QTc prolongation. **Conflict Code:** DD – Drug/Drug Interaction **Drug/Disease:** Util A: Telithromycin Util B: Pimozide Util C: **References:** Ketek Prescribing Information, Oct. 2004, Aventis Pharmaceuticals, Inc. Physicians' Desk Reference, Micromedex Healthcare Series, 2005.	√√√√ √√√√	_____	_____

BALLOT
CRITERIA RECOMMENDATIONS (November)
January 25, 2006

Criteria Recommendations	Approved	Approve as Amended	Rejected
1. Olanzapine / Olanzapine-Fluoxetine Combo Alert message: Therapeutic duplication of olanzapine products may be occurring. Zyprexa/Zyprexa Zydis (olanzapine) and Symbyax (olanzapine/fluoxetine) both contain the antipsychotic olanzapine. Caution should be exercised if prescribing these agents concomitantly. Conflict Code: TD – Therapeutic Duplication Drugs/Disease: Util A: Olanzapine/fluoxetine Util B: Olanzapine Util C: References: Symbyax Product Information, Oct. 2005, Eli Lilly and Company. Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
2. Fluoxetine / Olanzapine-Fluoxetine Combo Alert message: Therapeutic duplication of fluoxetine products may be occurring. Prozac/Prozac Weekly/Sarafem (fluoxetine) and Symbyax (olanzapine/fluoxetine) both contain the selective serotonin reuptake inhibitor fluoxetine. Caution should be exercised if prescribing these agents concomitantly. Conflict Code: TD – Therapeutic Duplication Drugs/Disease: Util A: Olanzapine/fluoxetine Util B: Fluoxetine Util C: References: Symbyax Product Information, Oct. 2005, Eli Lilly and Company. Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____
3. Olanzapine-Fluoxetine Combo / Over-utilization Alert message: Symbyax (olanzapine/fluoxetine) may be over-utilized. The recommended dosing range is 6mg/25mg to 12mg/50mg a day. The safety of doses above 18mg/75mg per day has not been evaluated. Conflict Code: ER – Over-utilization Drugs/Disease: Util A: Olanzapine/fluoxetine Util B: Util C: References: Symbyax Product Information, Oct. 2005, Eli Lilly and Company. Facts & Comparisons, 2005 Updates.	√√√√ √√√√	_____	_____

BALLOT
CRITERIA RECOMMENDATIONS (December)
January 25, 2006

Criteria Recommendations	Approved	Approve as Amended	Rejected
1. Long-Acting Beta Agonists / TA Alert message: Even though long-acting beta-2 agonists (LABA) decrease the frequency of asthmatic episodes, these medications may make the episodes more severe when they do occur. LABAs should not be the first medicine used to treat asthma. They should be added to the asthma treatment plan only if other medications do not control asthma. Conflict Code: TA - Therapeutic Appropriateness Util A Util B Util C Serevent Diskus Advair Diskus Foradil References: MedWatch - The FDA Safety Information and Adverse Event Reporting Program, 2005.	√√√√ √√√√	_____	_____
2. Atomoxetine / Therapeutic Appropriateness Alert message: There may be an increased risk of suicidal thinking in pediatric patients receiving Strattera (atomoxetine). The Food and Drug Administration is advising that all children and adolescents being treated with atomoxetine be closely monitored for clinical worsening, as well as agitation, irritability, suicidal thinking or behaviors, and unusual changes in behavior especially during the initial few months of therapy or when the dose is changed (increased or decreased). Conflict Code: TA – Therapeutic Appropriateness Drugs/Disease: Util A Util B Util C Atomoxetine References: MedWatch: The FDA Safety Information and Adverse Event Reporting Program, 2005.	√√√√ √√√√	_____	_____

The DUR Board recommendation is to begin utilization of carisoprodol criteria for the next cycle.

Carol Herrmann-Steckel, Commissioner (X) Approve ( ) Deny 3/15/06 Date

Kathy Hall, Deputy Commissioner (X) Approve ( ) Deny 3/14/06 Date

John Searcy, Medical Director (X) Approve ( ) Deny 03/14/2006 Date